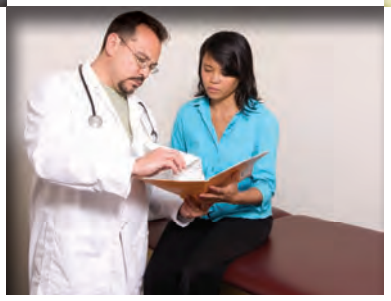
PointCare®

PointCare NOW™ System

8 MINUTES TO BETTER HIV/AIDS PATIENT CARE

CD4 + CD4% + HEMATOLOGY

ONE SAMPLE. ONE SYSTEM. ONE VISIT.



IMPROVE HIV/AIDS PATIENT CARE IN 8 MINUTES

Imagine the power of knowing in just eight minutes and in one easy report, 12 results critical to better disease management: CD4, CD4%, and selected hematology parameters. The FDA-cleared PointCare NOW system with flexible power options lets you test anywhere, anytime, enabling fast, easy set-up for clinic and mobile use. We supply all you need for testing in one box – from reagents, controls, and phlebotomy supplies to barcoded patient ID labels and printer paper. Unlike traditional instruments, the PointCare NOW system requires minimal training to operate. And there is no need for "cold-chain" transport, refrigeration, or protection from bright lights or extremes of temperature for reagents – all logistical obstacles are gone!

ONE SAMPLE. ONE SYSTEM. ONE VISIT. IT'S EASY:

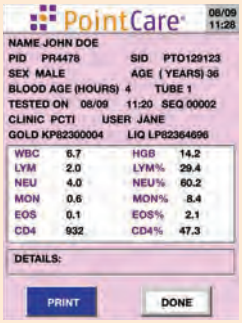
1. Draw

All phlebotomy supplies included

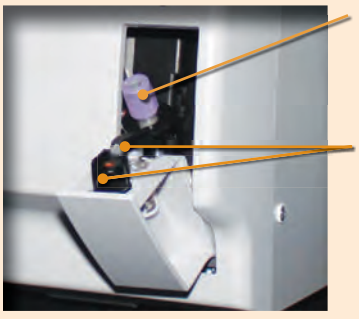
2. Test

- Scan sample ID with barcode reader
- Simply drop in sealed reagent vials & capped blood sample
- WALK AWAY!

3. Take Clinical Action NOW!



- Read 12 results in one simple report (printed & stored)
- Reduce loss-to-follow-up



Capped blood-sample tube
No exposure risk
No pipetting
No manual steps

Ready-to-use reagents

- Automated software interprets raw data
- No subjective interpretation of "dot plots"
- 8,000 results stored on board
- USB port to transfer results (USB flash drive included)

DESIGNED SPECIFICALLY FOR LOW-RESOURCE SETTINGS, NO OTHER DEVICE OFFERS THE SIMPLICITY, FLEXIBILITY, & IMMEDIACY OF THE POINTCARE NOW SYSTEM

- **Proven, field-tested technology** – Introduced in 2007, busy clinics around the globe, including the largest HIV/AIDS programs, use the FDA-cleared PointCare NOW system.
- **Comprehensive results in just 8 minutes** – CD4, CD4%, and hematology parameters, including white blood count (WBC), lymphocyte, neutrophil, monocyte, eosinophil, and hemoglobin.
- **Walk-away, sample-in/results-out automation** – There are no manual steps required, and it's easy to operate after only minimal training.
- **The ultimate in user safety** – This fully enclosed, automated system with closed-cap sampling offers significant biosafety features over other available CD4 systems. No hoods!
- **Heat-stable reagents & Daily Check™ controls** – Eliminate the considerable hidden costs of cold-chain shipping and refrigerated storage. No light-sensitivity.
- **Rugged system with flexible power** – Battery and solar option and fast, easy set-up for mobile use. Operational for patient testing 20 minutes after transport.
- **Easy logistics & supply chain with all you need for testing in one box** – All reagents, Daily Check controls, phlebotomy, and other necessary supplies required to run 100 patient samples.
  NO REFRIGERATION REQUIRED!

Serve More Patients, Reduce Loss-to-Follow-Up, & Improve Outcomes with the PointCare NOW System!

SEE THE WHOLE PICTURE:
the PointCare NOW system delivers on-the-spot results before the patient leaves the clinic

CD4 + CD4% + HEMATOLOGY TESTING = BETTER CLINICAL DECISIONS

Loss-to-follow-up has consequences far greater than the health of the individual patient. It wastes precious resources and exacerbates the HIV/AIDS crisis – increasing the chance of drug-resistant strains of infection and hampering efforts to reduce mother-to-child transmission of HIV. However, there is a simple, cost-effective way to reduce loss-to-follow-up and improve health outcomes: the PointCare NOW system.

No more logistical headaches sending samples to an off-site lab. No more waiting days or weeks only to find that the blood sample is damaged, the patient is impossible to locate, or she is too sick to return to the clinic. *With one sample, one system, one visit, and in just eight minutes, the PointCare NOW system gives you the essential information you need to make clinical decisions.*

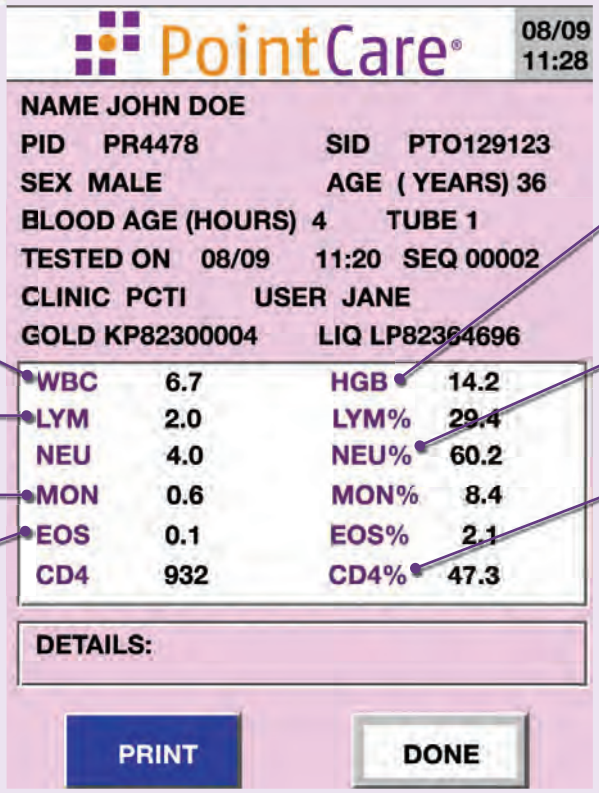
The system performs all data analysis automatically – there's no manual gating or interpretation of data required.

There is much more to proper management of HIV/AIDS patients than a regular evaluation of T-cell status. It requires assessment, diagnosis, and treatment of underlying health conditions. That's why the PointCare NOW system delivers 12 results total in one easy report:

- CD4/CD4%
- WBC
- Hemoglobin
- Lymphocyte, neutrophil, monocyte, eosinophil (count and percent for all)

Is it time to initiate or change antiretroviral therapy? Are there indicators of opportunistic infections or parasites? The system's CD4/CD4% and hematology parameters give you greater insight into the patient's overall health – on the spot, before he leaves the clinic – so you can follow up and treat accordingly.

POINTCARE NOW PARAMETERS FOR BETTER DISEASE MANAGEMENT



White blood cell count monitoring can help detect opportunistic infection.

Lymphocyte to **monocyte** ratio may help flag HIV patients co-infected with tuberculosis.

Eosinophils can be a valuable marker to flag and monitor parasitic infection.

Hemoglobin concentration can help identify anemia early to improve health outcomes.

Low **neutrophils** put HIV/AIDS patients at increased risk for bacterial and fungal infection.

CD4% is a critical parameter in pediatric *and* adult care

Unlike absolute CD4 values, CD4% values remain constant within the increasing or decreasing lymphocyte population. When viewed together, **CD4, CD4%, and lymphocyte** can be a more-accurate indicator of immune status than CD4 count alone, facilitating internal cross-checking of each CD4 patient report.

Visit **www.pointcare.net/publications/** for more information on the value of the CD4, CD4%, and hematology parameters on the PointCare NOW system, as well as references to relevant medical studies.

FDA-CLEARED POINTCARE NOW – SYSTEM SPECIFICATIONS

TECHNOLOGY

The FDA-cleared PointCare NOW system achieves its breakthrough performance in speed, simplicity, ease of use, and stability because developers chose proven optical-measurement techniques for its core technology and designed modular, injection-molded housings with few moving parts to create a robust instrument ideal for challenging environments and low-resource settings. The system has solid-state electronics, and comes pre-calibrated from the factory, eliminating the need for calibration by the operator.

The instrument platform combines two diagnostic systems in one rugged, small-footprint unit that the user operates like a hematology analyzer. Its fluidics system prevents operator contact with blood, blood or fluid aerosols, and liquid waste, therefore eliminating the costly need for a biosafety hood, which is mandatory for traditional flow cytometry systems. The operator takes a capped phlebotomy blood-sample tube and, with the cap still in place, inserts the tube into a receiving slot in the instrument. There are also two additional slots for reagent vials (sufficient for 20 samples). The instrument takes the tube inside automatically, and the door closes and locks to prevent user interaction with fluids. In a fully automated process, the system pierces the cap, withdraws a precise aliquot of whole blood, and biochemically processes the sample internally to give the results.

The door opens after eight minutes and the capped tube is returned to the user after the results are displayed on the instrument screen. A printer comes standard with every system to generate a paper record of results. Waste generated during the test is decontaminated automatically and confined to a sealed container. Users are not exposed to the biohazardous conditions encountered with standard methods of CD4 lymphocyte enumeration because operators do not remove the blood-tube cap, they do not pipette the sample and reagents into open tubes, they do not vortex mix in an open tube, and there are no contaminated reaction tubes and pipette tips for disposal.

The PointCare NOW system delivers 12 results in just eight minutes in one easy report that can be printed and stored. It generates a white cell differential, a total white cell count, and a hemoglobin concentration measurement, employing the same proven hematology technology used in reference labs. The system also provides both absolute CD4 count and CD4%, expressed as a percent of total lymphocytes. This is achieved by using a label to change the natural light scatter characteristics of the CD4 subclass of lymphocytes to perform CD4 enumeration. The label consists of anti-CD4 antibodies coupled to nano-sized gold particles. PointCare achieves a fast (< 1 minute) antibody reaction time by adding a proprietary charge-neutralizing reagent to the whole blood.

An axial light loss detector identifies any cell carrying the CD4 antigen on the basis of the granularity added by the colloidal gold label. The system also employs a forward scatter detector in combination with the axial light loss detector to eliminate monocyte interference from the CD4 lymphocyte count and provide a differential count for four classes of white blood cells (lymphocytes, monocytes, neutrophils, and eosinophils). The optical system uses a long-lifetime LED (light emitting diode) light source. LED light sources consume less power and tend to be more stable than the lasers used in traditional instruments, enabling long, service-free operation. Power consumption for the total system is approximately 60 watts on average, which is much lower than the multi-kilowatt levels of power consumption encountered with laboratory flow cytometers.

The PointCare NOW system provides internal and external measures of quality control to ensure proper test performance for every sample. Onboard controls automatically monitor and record more than 50 check points during every sample run. When appropriate, the system flags any abnormality that may require further clinical intervention from the laboratory or physician. This eliminates errors by the operator in performing and reporting the test result, and reduces requirements of clinician time to troubleshoot and interpret inconclusive reports. Data-analysis software automatically identifies dot plot clusters for cell enumeration, as well as abnormal clusters. When abnormal clusters occur, and accurate cell enumeration is compromised, the software alerts the user via a screen message, and does not report a result. Operators are locked out of this software and cannot alter gates, results, or flag messages, thus assuring the highest-quality results at all times. External Daily Check controls are included with test kits at no extra charge to ensure that the system pipettes, pumps, valves, and optics are operating as specified. Users should run Daily Check controls at the beginning of each workday before performing sample analysis.

POINTCARE NOW CORRELATION

	CD4 Count/System	Hematology*/System
2007 POINTCARE NOW 510(K) MULTI-COUNTRY STUDY **Samples:** 161 **Sites:** 3	**Pearson R:** 0.989 EPICS® XL™, FACSCalibur™ & AuRICA™	**Pearson R:** 0.956 to 0.994 Sysmex
2008/09 NATIONAL PUBLIC HEALTH LAB OF HAITI STUDY **Samples:** 81 **Sites:** 3	**Pearson R:** 0.924 FACSCount™	**Pearson R:** 0.975 to 0.991 Sysmex

*** WBC, HGB, NEU, LYM, EOS, MON**

POINTCARE NOW PRECISION

The 2008/09 study at the National Public Health Laboratory of Haiti ran a CD4 Low Control 20 times in order to evaluate repeatability. The CD4 count precision (CV) from this study was ***13.5%****.*

After the release of PointCare NOW System Version 2 in 2010, PointCare conducted an internal study to reevaluate precision for Low and Normal levels of CD4. Precision (CV) was ***≤ 9.0%*** *at the Low level, and* ***≤ 4.9%*** *at the Normal level when run 20 times each on two instruments.*

SYSTEM INFORMATION

Customer Installation Package

With purchase of an instrument the following is provided standard:

- The PointCare NOW instrument
- Printer
- Barcode reader
- USB flash drive
- Preventive-maintenance kit
- User manual
- Reusable waste container
- On-site installation & operator training
- 1-year limited warranty

Flexible Power Options

- Uninterruptible Power Supply (UPS) – 110 V or 220 V
- Portable battery power system
- Solar charge system

Optional Accessories

- Portable travel case (holds instrument, printer, barcode reader, power cords, reagents, etc.)
- Portable battery pack
- Folding solar panel

Required Materials Not Provided

- None

Space Requirements

Instrument:

- Height: 35 cm
- Width: 25 cm
- Depth: 34 cm
- Weight: 12 kg

Printer:

- Height: 14 cm
- Width: 16 cm
- Depth: 25 cm
- Weight: 2.7 kg

Regulatory Status

- FDA/IVD cleared
- CLIA moderate-complexity rating
- CE marked
- ISO 13485:2003 certified manufacturer
- UL listed

SAMPLE & RESULT SPECIFICATIONS

Sample Information

- Sample volume: 40 µL whole blood
- Sample tube: 2 mL vacuum K2 EDTA blood-collection tubes provided (system also accepts 3 and 4 mL tubes)
- Sample stability: 8 hours from time of draw

Specifications

- Time to result: 8 minutes for all results
- Throughput: 50 samples per day
- Batch size: One; samples are run individually

Results Provided

- CD4 absolute count & percent
- WBC
- Hemoglobin concentration
- Lymphocyte count & percent
- Neutrophil count & percent
- Monocyte count & percent
- Eosinophil count & percent

PRECISION & REPORTABLE RANGES

PARAMETER	REPORTABLE RANGE	UNITS	PRECISION LEVEL	CV
CD4 Count	50 to 6,000	cells/µL	600/µL	< 10%
CD4 Count*	–	–	100 to 200/µL	< 15%
CD4 Percent (%)	3.0 to 77.0	%	–	–
WBC	0.5 to 40.0	10^3/µL	6.0 10^3/µL	< 3%
Hemoglobin	1.0 to 20.0	g/dL	12 g/dL	< 2%
Lymphocyte Count	0.2 to 15.0	10^3/µL	2.0 10^3/µL	< 5%
Lymphocyte Percent (%)	12.0 to 80.0	%	–	–
Neutrophil Count	0.2 to 23.5	10^3/µL	2.0 10^3/µL	< 3%
Neutrophil Percent (%)	12.0 to 80.0	%	–	–
Monocyte Count	0.0 to 5.9	10^3/µL	1.0 10^3/µL	< 7%
Monocyte Percent (%)	1.5 to 20.3	%	–	–
Eosinophil Count	0.0 to 5.8	10^3/µL	0.3 10^3/µL	< 15%
Eosinophil Percent (%)	0.6 to 60.0	%	–	–

*** Determined by CD4NOW Control Low**

LINEARITY & CARRYOVER

PARAMETER	RANGE	UNITS	PEARSON R	% CARRYOVER
WBC*	0.1 to 42.3	10^3/µL	0.999	0.10%
Hemoglobin*	0.0 to 18.3	g/dL	0.999	0.5%

*** System linearity for all other parameters traceable to WBC; system carryover below threshold for all other parameters**

REAGENT KIT INFORMATION

(Test Kit/Consumables)

PointCare NOW Reagent Kit 100 contains all reagents, controls, and supplies needed for 100 tests:

- 3 CD4NOW LiquiPacks – Containing diluent, lysing reagent, and cleaning solution for 100 tests
- 1 CD4NOW Gold Pack – Containing colloidal gold reagent for CD4 labeling (for 100 tests)
- Daily Check Controls – 3 tubes each of Low and Normal levels
- All phlebotomy supplies – Tourniquets, needles, needle holders, gloves, blood-collection tubes, alcohol swabs, gauze pads
- All other necessary supplies – Barcoded patient ID labels, waste tablets, printer paper, and ribbon

Note: *No cold-chain or refrigeration required. Reagents & controls are not light sensitive*

Shelf Life

Reagents:

- 12 months from date of manufacture when stored at 2° to 30° C (36° to 86° F)
- Transient exposure (shipping delay or temperature excursion) of 10 days at 50° C (122° F)

Daily Check Controls:

- 6 months from date of manufacture when stored at 2° to 42° C (36° to 108° F)
- Transient exposure (shipping delay or temperature excursion) of 10 days at 50° C (122° F)

Quality Control Information

- Internal: 53 check points monitored and recorded on every sample
- External: Daily Check Low and Normal levels run once a day
- Validation results available upon request
- Levey-Jennings plots generated automatically
- Log for QC data recorded as mean, SD, and CV
- Additional hematology and CD4 external controls available in two levels

System Operation

Ease of Use:

- Fully automated – No manual steps for pipetting, incubation, vortexing, etc.
- Barcode reader & labels – Simple sample tracking and reagent management
- Factory calibrated – Low power consumption LED (no laser); no gain adjustments or color compensation required

Instrument Software:

- Data storage – 8,000 onboard patient records; unlimited patient records transferable to USB
- Automated data analysis – No manual gating or data interpretation
- Menu languages – English, French, Spanish, Portuguese, and Indonesian (in development)

User Safety:

- No exposure – Closed-tube sampling; no exposure to contaminated blood
- Closed waste handling – All hazardous waste is contained and decontaminated for safe disposal

CUSTOMER SUPPORT

At PointCare, we're proud of our record of quality, performance, and customer support. We listened to users and designed everything – the PointCare NOW instrument and kits, ordering logistics, service, and support – to make it easy for customers in resource-limited locations. When you purchase a PointCare NOW system, you can count on us to help you be successful. On-site installation services and user training come standard. And help is just a phone call, or e-mail away. Our typical response time is within one business day. Our field-service staff members are strategically located around the globe to support our customers.

Call customer support at: **+1 800.346.6906**, or from outside North America: **+1 508.281.6925**
E-mail: **customersupport@pointcare.net**

"WE'RE A MILE AWAY FROM THE RAINFOREST WHERE THERE ARE MOUNTAIN GORILLAS, RIGHT ON THE BORDER BETWEEN UGANDA AND THE DEMOCRATIC REPUBLIC OF CONGO.

There aren't any tarmac roads here, there isn't any public transport, and lots of the patients live a day's walk from the hospital. Many of them live a subsistence existence and they can't afford to get here.

So we drive to remote communities in our mobile HIV outreach clinic vehicle equipped with the PointCare NOW system, and are up-and-running testing patients within 20 minutes of arrival.

Before we had this machine, we'd see somebody in the clinic, then we'd have to see them on another day to collect a blood sample. We had a system of motorcycle riders that went 'round all of our outreach sites on a particular day to collect samples. They would have to ride for four hours along a muddy road through the Impenetrable Forest, to a laboratory on the other side, where we could get them tested.

It took us three days to get the result, and we couldn't get it back to the patient until we saw them again two weeks later. Now, with this simple piece of technology, we can deal with problems immediately.

We're able to diagnose [AIDS] early, manage it early, and keep people living with HIV fit and well... we've been able to change HIV from being a death sentence into something that people can live with and lead productive lives."

– Dr. Paul Williams, Bwindi Community Hospital, Uganda

THE POINTCARE NOW SYSTEM ADVANTAGE	
Absolute CD4 T-Cell Count & CD4%	✓
Lymphocyte, Neutrophil, Monocyte, Eosinophil (Count and Percent for All)	✓
Simultaneous Hematology, CD4, & CD4%	✓
No Reagent Cold-Chain or Refrigeration	✓
No Reagent Light Sensitivity	✓
Easy to Use with Only Minimal Training	✓
Fully Automated System	✓
No Manual Gating Required	✓
No Manual Pipetting Required	✓
Extensive Onboard Data Storage & Management	✓
Closed and Decontaminated Waste System	✓
Simple & Low Power LED Light Source	✓
Low Energy Consumption	✓
Flexible Electrical Power (Battery/Solar Option)	✓

An industry first ✓

ABOUT POINTCARE TECHNOLOGIES

Our mission is to bring appropriate point-ofcare diagnostics to resource-limited settings. We design, manufacture, and market our products to provide clinicians with the rapid results they need to improve patient care. PointCare is a privately held, FDA-registered, ISO-certifi ed company.

Ordering information:

Description	Part No.
PointCare NOW System Installation Package (includes instrument, barcode reader, USB flash drive, preventive-maintenance kit, user manual, reusable waste container, on-site installation, & operator training, 1-year limited warranty)	**36008**
PointCare NOW Reagent Kit 100 (contains all reagents, controls, and supplies needed for 100 tests)	**36000**
Uninterruptible Power Supply 110 V	**25052**
Uninterruptible Power Supply 220 V	**25054**
Portable Battery Power System	**25161**
Solar Charge System	**10214**

To order, obtain product information, or for any other inquires please contact:
Telephone: **+1 508.281.6925**
Fax: **+1 508.281.6930**
E-mail: **sales@pointcare.net**

Headquarters: USA

PointCare Technologies, Inc.
257 Simarano Drive, Suite 101
Marlborough, MA 01752 USA
Telephone: +1 508.281.6925
Fax: +1 508.281.6930
E-mail: info@pointcare.net

www.pointcare.net

Specifications subject to change without notice
F-291 Rev C

©2010 PointCare Technologies, Inc.
ISO 13485:2003

PointCare Field Service & Support

Regional Field-Service Contacts:

Caribbean (US-based)	Senegal
Haiti	South Africa
Indonesia	Tanzania
Malawi	Thailand
Malaysia	Uganda
Nigeria	Zambia

Our list of regional offices and distributors is growing. Check our Web site for the latest contact details at **www.pointcare.net/contact**, or call **+1 508.281.6925**.